UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
THIS DOCUMENT RELATES TO:	Master File No. 01-CV-12257-PBS
STATE OF NEVADA v. AMERICAN HOME PRODUCTS CORP., et al., Civil Action No. 02-12086-PBS	Judge Patti B. Saris

INDIVIDUAL MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANT ASTRAZENECA PHARMACEUTICALS LP'S MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES & RULES

PRELIMINARY STATEMENT

Defendant AstraZeneca Pharmaceuticals LP ("AstraZeneca")[1] respectfully submits this individual memorandum of law in further support of its motion for summary judgment. As set forth in the Defendants' joint memorandum of law ("Joint Memorandum" or "Joint Mem."), Defendants are entitled to summary judgment on all claims brought by the State of Nevada (the "State" or "Plaintiff") in its Amended Complaint ("Am. Compl."). AstraZeneca is also entitled to summary judgment on the State's claims brought against it for the independent reasons set forth below: (1) the State was not deceived or defrauded with respect to the pricing of AstraZeneca's drugs; (2) AstraZeneca did not cause, and the State did not suffer, any ascertainable losses due to AstraZeneca's alleged misconduct; and (3) there is no evidence in the record to support the State 's "Best Price" claims.

[1] Although named as Defendants, Zeneca, Inc. and AstraZeneca PLC have never been served with the State of Nevada's Amended Complaint. The entity identified in the Amended Complaint as AstraZeneca U.S. does not exist.

FACTUAL BACKGROUND[2]

As permitted under the federal Medicaid guidelines, Nevada's Medicaid program includes a prescription drug benefit that is administered by the State's Medicaid agency. *See* Am. Compl. ¶ 121. Like all other states, Nevada has discretion in determining the payment methodology and payment rate for prescription drugs covered by its Medicaid program, subject to federal requirements. *See* Joint Mem. at 3. Federal law requires that states, in setting reimbursement rates, balance the interests of patients, pharmacists, and the government in achieving efficiency, economy, and quality of care, and in enlisting sufficient providers to provide access to care. *See* 42 U.S.C. § 1396a(a)(30)(A).

With respect to AstraZeneca's self-administered drugs ("SADs") covered under the Nevada Medicaid program—which are at the core of the State's claims against AstraZeneca—all prescribing decisions are made by physicians. *See* AstraZeneca 56.1 Stmt. ¶ 1. In turn, pharmacists dispense these drugs, and are subsequently reimbursed by Nevada Medicaid. *See id.* While the physician makes the decision as to which SAD to prescribe, he or she does not have an incentive to choose one drug over the other based on the Average Wholesale Price ("AWP")/acquisition cost "spread" because the physician does not pay for and is not reimbursed for the drug. *See id.* ¶ 2. The pharmacist must dispense the specific branded drug prescribed by the physician, and does not have the ability to dispense a different drug based on the "spread" he or she would receive via reimbursement. *See id.* ¶ 3. Because there is a clear disconnect between *incentive* (the receipt of reimbursement) and *opportunity* (the decision regarding which

[2] AstraZeneca incorporates by reference the joint Defendants' Statement of Undisputed Material Facts in Support of Defendants' Motion for Summary Judgment ("Joint 56.1 Stmt."). Facts specific to AstraZeneca are set forth in its individual Local Rule 56.1 Statement of Undisputed Material Facts in Further Support of Defendant AstraZeneca Pharmaceutical LP's Motion for Summary Judgment ("AstraZeneca 56.1 Stmt.").

SAD to dispense), Nevada's core theory of liability—in which manufacturers "market the spread" in an attempt to increase market share—is illogical as to AstraZeneca's SADs. *Id.* ¶ 4.

From 1991 to 2004, the top five AstraZeneca SADs (not subject to a Federal Upper Limit ("FUL") through 2004) prescribed and reimbursed for under the Nevada Medicaid program were: (1) Seroquel (quetiapine); (2) Prilosec (omeprazole); (3) Nexium (esomeprazole); (4) Pulmicort Respules (budesonide inhalation suspension); and (5) Plendil (felodipine). *See id.* ¶ 5. These five drugs comprised over 80% of the State's total Medicaid expenditures for AstraZeneca drugs during this period. *See id.* For this time, the "spread" between AWP and Wholesale Acquisition Cost[3] ("WAC") for all of AstraZeneca's Medicaid-covered drugs, including the top five SADs discussed above, was either 20 or 25 percent. *See id.* ¶ 7.

In addition to federal funding, the Nevada Medicaid program receives rebate payments directly from the Defendant drug manufacturers that reduce the ultimate cost the State pays for pharmaceuticals. *See* 42 U.S.C. § 1396r-8(a)(1), (b)(2) & (3). The rebates range from a minimum of 11 percent of a drug's Average Manufacturer Price ("AMP") to considerably more for certain drugs, depending on the drug's reported "Best Price." *See* 42 U.S.C. § 1396r-8(c)(1) & (3). These rebate payments—which are ignored by the State and its expert in their theory of liability—reduce the State's ultimate costs for drugs reimbursed on behalf of Medicaid beneficiaries to levels *substantially below* its payments to pharmacies. For example, comparing the acquisition costs to Nevada pharmacies of AstraZeneca's top five Medicaid-covered drugs to the net reimbursements paid by the State's Medicaid program—taking into account the Medicaid

[3] The State and its expert, Dr. Raymond Hartman, use Wholesale Acquisition Cost as a proxy for the actual acquisition costs of Nevada pharmacies. (*See* AstraZeneca 56.1 Stmt. ¶ 6). For the sake of addressing the State's allegations, AstraZeneca's expert, Joel Winterton, does likewise.

"Best Price" rebates paid by AstraZeneca—the average net Medicaid reimbursement paid by the State was between 8.5 and 41.4 percent *less* than what Nevada pharmacies paid to acquire these drugs. *See* AstraZeneca 56.1 Stmt. ¶ 8. Comparing the pharmacy acquisition cost to the State Medicaid program's net cost for Seroquel, taking into account Medicaid rebates, the State paid roughly 17 percent *less* than did Nevada pharmacies for this AstraZeneca product. *Id.* ¶ 9.

In addition, it is undisputed that Nevada pharmacies are not fully compensated for their dispensing costs by the dispensing fees paid by the State's Medicaid program ($4.76 in 2004). *See id*. ¶¶ 10-12; Joint Mem. at 21, n.15. Taking into account these inadequate dispensing fees—i.e., comparing the dispensing fees paid by the State to the dispensing costs incurred by pharmacies—Nevada pharmacies incurred a small to substantial *loss* in dispensing the top five Medicaid-covered AstraZeneca drugs. For example, in 2004, Nevada pharmacies incurred a net average loss of roughly 3 percent in dispensing AstraZeneca's top five drugs under the State's Medicaid program—when the underpayment of dispensing fees is taken into account. *See id.* ¶ 13. More specifically, retail pharmacies in the State of Nevada in 2004 incurred a net loss, on average, of 2 percent when dispensing the drug Seroquel to Medicaid beneficiaries. *Id.* ¶ 14.

ARGUMENT

A. AstraZeneca Should be Granted Summary Judgment on All of the State's Claims Because the State Cannot Establish That It Was Deceived

To prove a claim under Nevada's Deceptive Trade Practices Act ("DTPA") or Nevada's Medicaid Fraud statute, the State—and the other parties on whose behalf it brings claims—must be able to point to some evidence of deception or fraud. *See Scaffidi v. United Nissan*, 425 F. Supp. 2d 1172, 1185 (D. Nev. 2005) (granting summary judgment for defendant on a DTPA claim where the plaintiff could not demonstrate the existence of a false representation); NEV. REV. STAT. § 598.0993; NEV. REV. STAT. § 422.540 (Medicaid Fraud statute requires that the offense is committed "with the intent to defraud.").

Courts interpreting Nevada law have "consistently found that deceit and other actions for fraud require justifiable reliance on the part of the party asserting the claims." *G.K. Las Vegas L.P. v. Simon Prop. Group, Inc.*, No. CV-S-04-1199-DAE-GWF, 2006 U.S. Dist. LEXIS 81943, at *32 (D. Nev. Sept. 29, 2006) (emphasis added); *accord Collins v. Burns*, 741 P.2d 819, 821 (Nev. 1987) (holding that lack of justifiable reliance is a bar to an action for the tort of deceit). In a situation where a plaintiff has knowledge of the existence of the representation or practice that is purportedly actionable—as is the case here—reliance on such a representation or practice is not justifiable. *See Collins*, 741 P.2d at 821 (holding that reliance is not justifiable where "the recipient has information which would serve as a danger signal and a red light to any normal person of his intelligence and experience").

The State has not demonstrated that Defendants engaged in conduct that defrauded or deceived the State (or third-party payers.) As discussed in Defendants' Joint Memorandum, the State and other payers were not deceived regarding AWP. The factual record establishes that

AWP was known to be a pricing benchmark, rather than an *actual* average of wholesales prices. *See* Joint Mem. at 12-15, 18-30. Third-party payers possessed such knowledge as well. *See id.* at 8 n.9. Thus, because the State's central and essential allegation of deception cannot be established through evidence, summary judgment is warranted for all Defendants on all of Nevada's claims.

Moreover, with respect to AstraZeneca's drugs, the record demonstrates that: (1) the underlying economics and distribution mechanics for AstraZeneca's drugs render the Plaintiff's theory of liability nugatory as to AstraZeneca's branded pharmacy-dispensed products; (2) the spreads between acquisition costs and AWPs for AstraZeneca's self-administered drugs are well within what the State's own expert has acknowledged as an expected yardstick by market participants; and (3) AstraZeneca's alleged misconduct could not have caused the State to suffer injury because, taking into account Medicaid rebates, the State's net costs for AstraZeneca's drugs were actually *less* than the acquisition costs of Nevada pharmacies.[4]

1. **Plaintiff's Spread Manipulation Theory Has No Application as to AstraZeneca's Branded Pharmacy-Dispensed Products**

The State claims that AstraZeneca engaged in a scheme to "increase defendants' profits at the expense of Patients and programs such as the Nevada Medicaid Program" by manipulating the spread between pharmacy acquisition costs and AWP. Am. Compl. ¶ 136. But the State can point to no facts or evidence that demonstrate that AstraZeneca engaged in such manipulation or had any economic incentive to do so. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986)

[4] In addition, it is clear the State was not deceived regarding the prices of AstraZeneca's products because non-Medicaid State entities were purchasing various AstraZeneca drugs at prices *below* the Nevada Medicaid ingredient cost reimbursement rate. AstraZeneca 56.1 Stmnt. ¶ 15.

(noting that Rule 56 "must be construed with due regard not only for the rights of persons asserting claims and defenses that are adequately based in facts to have those claims and defenses tried to a jury, but also for the rights of persons opposing such claims and defenses to demonstrate in the manner provided by the rule, prior to trial, that the claims and defenses have no factual basis").

The State chose to use AWP in its Medicaid reimbursement methodology and, while a difference between the published AWPs and actual acquisition costs of AstraZeneca drugs—the alleged "spread"—might result in greater compensation to Nevada pharmacists as a result of the State's choice, AstraZeneca did not have any incentive to increase pharmacy margins. There is no evidence to the contrary and the record demonstrates that the market conditions and distribution process for AstraZeneca's products eliminate any such incentive on the part of AstraZeneca. *See* AstraZeneca 56.1 Stmt. ¶ 4. As discussed in the Factual Background Section, *supra* at 2, a "spread" on branded outpatient drugs could not result in additional sales or expanded market share for a manufacturer because pharmacists have no power to influence the prescribing decisions of doctors. According to Defendants' joint expert Gregory K. Bell, the idea that manufacturers would purposefully create a "spread" on SADs makes no sense. *See id.* 16; Joint Mem. at 11-12. Such a conclusion is consistent with the finding of this Court in the MDL class-action litigation, in which the Court concluded that retail pharmacies cannot impact market share for branded outpatient drugs. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 74 (D. Mass 2005).

2. The Spreads Between Acquisition Costs and AWPs for AstraZeneca's Products Are Within Plaintiff's Expert's Expectation Yardstick

The fact that the State knew, or should have known, that the AWPs for AstraZeneca's drugs were greater than retail pharmacies' actual acquisition costs is further confirmed by the analysis prepared by the State's own expert, Dr. Raymond Hartman. As part of his analysis in the MDL class-action litigation, Dr. Hartman found that payers are aware that AWPs are greater than Average Sales Prices ("ASPs"), but as an important publicly available price, they rely on AWPs to bear a predictable relationship to ASPs (Hartman's "yardstick theory"). *See* AstraZeneca 56.1 Stmt. ¶ 17. Consequently, Dr. Hartman went on to attempt to determine what the expectation was for that relationship—i.e., ASPs compared to the corresponding published AWPs. Dr. Hartman calculated this reasonable expectation to be a 30 percent spread between AWP and ASP**,** which he has described as a liability threshold.[5] *Id.* ¶ 18. Not only would Dr. Hartman's yardstick apply to third-party payers on whose behalf the State asserts claims, but Dr. Hartman specifically testified that state Medicaid agencies are market participants that would have such an expectation. *Id.* ¶ 19. Thus, the State's own expert explicitly acknowledges that Nevada Medicaid and third-party payers must have known that AWPs were higher than pharmacies' actual acquisition costs.

Moreover, the "spreads" on AstraZeneca's self-administered drugs are well within the 30 percent threshold identified by Dr. Hartman. *See id.* at ¶ 7. Over the period of Plaintiff's allegations, the "spread" between AWP and WAC for all of AstraZeneca's Medicaid-covered

[5] Defendants, including AstraZeneca, dispute the validity of Dr. Hartman's yardstick or expectation theory, whether it is applied in the instant case or the MDL class-action litigation. His theory is presented here, however, solely for the purpose of demonstrating that, even under the State's own expert's theory of liability, the spreads between AWP and acquisition cost for AstraZeneca's drugs are not actionable.

drugs was either 20 or 25 percent. *Id.* Because the spreads between the AWPs and the actual acquisition costs (using WAC as a proxy) of AstraZeneca's drugs were within the bounds of what would have been expected by the State and Nevada third-party payers—as acknowledged by the State's own expert—the State cannot establish that it has been deceived or that the AWPs for AstraZeneca's drugs caused the State any loss.

3. **AstraZeneca Did Not Cause the State to Suffer an Injury Because the Net Prices Reimbursed by the State for AstraZeneca's Self-Administered Drugs Were Actually Less Than the Pharmacies' Acquisition Costs**

Surprisingly, in this litigation, the State asserts claims against AstraZeneca in situations where the net Medicaid reimbursements paid by the State to Nevada pharmacies were actually significantly less than the amounts it cost these pharmacies to acquire the relevant AstraZeneca drugs. Under Dr. Hartman's analysis, liability is premised on the State being caused to pay an inflated reimbursement amount. *See id.* ¶ 20. In other words, the basis of Dr. Hartman's liability theory is that Defendants' alleged misconduct caused the State to reimburse pharmacies at levels above their acquisition costs. *Id.* In Dr. Hartman's "but-for" world, the State should have been reimbursing pharmacies at the exact dollar amount paid by the pharmacies to acquire the relevant Medicaid-covered drugs. *Id* ¶ 21. However, when Medicaid rebates are factored into this equation for AstraZeneca's drugs, not only is the State not making reimbursement payments at levels higher than pharmacies' acquisition costs, but the State is actually paying significantly less. *See id.* ¶ 8.

AstraZeneca's expert, Mr. Winterton, conducted an analysis that compares the acquisition costs to Nevada pharmacies of AstraZeneca's top five Medicaid-covered drugs to the net reimbursements paid by the State's Medicaid program, taking into account the Medicaid

"Best Price" rebates paid by AstraZeneca to the State. *See id.* Significantly, Mr. Winterton finds that, for these top-five drugs, the average net Medicaid reimbursement paid by the State was between 8.5 and 41.4 percent *less* than what Nevada pharmacies paid to acquire these drugs. *Id.* Accordingly, it is indisputable that—when Medicaid rebates are taken into account—the net Medicaid reimbursements made by the State are actually *substantially lower* than the costs incurred by Nevada pharmacies to acquire AstraZeneca's drugs. *Id.* ¶ 9. In such situations, there can be no viable argument that AstraZeneca's alleged misconduct caused the State to suffer an injury through higher Medicaid reimbursements.

B. AstraZeneca Should be Granted Summary Judgment on All of the State's Claims Because the State Cannot Prove That It Suffered an Ascertainable Loss

The State's claims also fail because it cannot demonstrate a cognizable injury or loss. The Nevada Supreme Court has held that plaintiffs bringing fraud claims must plead loss or injury. *See Bulbman, Inc. v. Nevada Bell*, 825 P.2d 588, 592 (Nev. 1992) (holding that loss is a requirement for "claims in fraud"). The remedies sought by Plaintiff require it to demonstrate a cognizable injury. The State seeks restitution for its own claims—and the claims brought on behalf of Nevada residents—pursuant to the NDTPA (Counts I and II). *See* Am. Compl. ¶¶ 424, 438. Such relief is unavailable where there is no showing of loss or injury. *See Mertens v. Hewitt Assocs.*, 948 F.2d 607, 613 (9th Cir. 1991) (explaining that the remedy of "restitution requires that there be a direct link between the loss complained of and the recovery sought"). Moreover, the State's NDTPA claim for civil penalties for injuries suffered by elderly state residents (Count II) is predicated on its ability to demonstrate that these residents were injured as

a result of Defendants' alleged misconduct.[6] *See* Am. Compl. ¶ 431 ("This Claim is brought for civil penalties and injunctive relief to prevent the harm caused to Elderly patients in Nevada").

The State cannot show that it suffered a loss because it cannot show that any alleged misconduct by AstraZeneca caused it to overpay Nevada pharmacists for AstraZeneca drugs. First, the State has not produced any data sufficient to show that it incurred an ascertainable loss. Second, the State's causes of action are predicated on the basic assumption that pharmacies were receiving windfall profits as a result of Defendants' purported fraudulent scheme. *See* AstraZeneca 56.1 Stmt. ¶ 22. Mr. Winterton, however, conducted an analysis of the net amounts that Nevada pharmacies received in reimbursement from the State for dispensing AstraZeneca's drugs under the Medicaid program, and found that these pharmacies barely broke even. *Id*. ¶ 13. Indeed, in many instances, these pharmacies actually lost money in dispensing AstraZeneca's drugs to Nevada Medicaid beneficiaries. Because the State could not have realistically lowered its reimbursement rates for these products—without Nevada pharmacies suffering a loss each time they dispensed an AstraZeneca product—there is no ascertainable loss suffered by the State.

1. The State Has Produced No Evidence Demonstrating That It Suffered a Loss For Certain Claims

Despite having years to develop and refine its liability and damage analysis in this litigation, the State has failed to produce data sufficient to show that it suffered an ascertainable loss for a number of its individual claims. Not surprisingly, Dr. Hartman has failed to provide an expert analysis to support damages on these claims.

[6] The State's inability to demonstrate loss can also be characterized as an Article III standing defect because without proof of loss, the State has no standing to bring suit. The Supreme Court has "repeatedly noted that in order to establish Article III standing, '[a] plaintiff must allege personal injury fairly traceable to the defendant's allegedly unlawful conduct." *Dep't of Commerce v. U.S. House of Reps.*, 525 U.S. 316, 329 (1999) (citing *Allen v. Wright*, 468 U.S. 737, 751 (1984)); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992).

As discussed above, loss is a material element of all of the State's causes of action. It is well-established that where a non-moving party has failed to carry its burden of proof on an essential element—as the State has done here regarding loss—summary judgment must be granted. *See* Joint Mem. at 6; *Celotex*, 477 U.S. at 327. Indeed, where a plaintiff is unable to demonstrate proof of loss at this advanced stage of a litigation, courts have found it appropriate to grant summary judgment. *See, e.g., Stoneman v. Morgan, Cameron & Weaver, P.C.*, 44 F. App'x. 846 (9th Cir. 2002) (upholding summary judgment on a Nevada consumer protection claim where the plaintiff did not present evidence of an ascertainable loss); *Goins v. JBC & Assocs., P.C.*, 352 F. Supp. 2d 262, 275-76 (D. Conn. 2005) (denying plaintiff summary judgment on a Connecticut consumer protection claim where the plaintiff did not present evidence of a measurable loss).

As an initial matter, the State cannot show that it suffered tangible damages on claims related to purported payments by the Nevada Medicaid program to cover the 20 percent Medicare Part B co-payment made on behalf of individuals who are dually-eligible for Medicare and Medicaid benefits. *See* AstraZeneca 56.1 Stmt. ¶ 23. Because Dr. Hartman was not provided pertinent data by the State, he was unable to calculate damages for these co-payments. *See id.* Indeed, Nevada has produced no data relating to physician-administered drugs and, thus, Dr. Hartman does not attempt to calculate damages for these drugs. *See id.* ¶ 24; Joint Mem. at 7-8. Nevada also failed to produce any claims data for claims after 2002, and Dr. Hartman does not calculate damages or penalties for this time period. *See id.* ¶ 25. Finally, Dr. Hartman's report is completely silent as to claims and losses suffered by unnamed third-party payers—a

clear indication that the State cannot show that these payers suffered an ascertainable loss. *See id.* ¶ 26.

2. **The State's Reimbursement Decisions Were an Effort to Balance Reimbursement Levels and Access**

Section 30(A) of the Medicaid Act, 42 U.S.C. §1396(a)—often referred to as the equal access provision—sets a floor on the amount that state Medicaid agencies can reimburse pharmacies: they cannot reimburse providers below an amount that threatens access to care for the state's citizens. *Id.*; *see Arkansas Med. Soc'y, Inc. v. Reynolds*, 6 F.3d 519, 530 (8th Cir. 1993) (explaining that the purpose of this provision is to "ensure adequate access and quality of care in the context of … Medicaid providers"). Relevant to this requirement, the financial situation of rural pharmacies in Nevada was, and is, so precarious that a reduction in Medicaid reimbursement rates would have caused significant numbers of the State's pharmacies to close, threatening access to care for rural Nevadans. *See* AstraZeneca 56.1 Stmt. ¶ 27. Forcing these rural pharmacies to realize a loss in dispensing drugs under the Medicaid program implicates this statutory provision and, thus, would be contrary to federal law. *See, e.g.*, *Orthopaedic Hosp. v. Belshe*, 103 F.3d 1491, 1467 (9th Cir. 1997) (explaining that for payments to providers to be consistent with the equal access provision, "they must approximate the cost of quality care provided efficiently and economically").

The State's bald assertions that Nevada pharmacies are making "substantial profits" on the basis of AstraZeneca's alleged misconduct is not borne out by the available facts. Am. Compl. ¶ 141. As explained by Mr. Winterton, it is the sum of the ingredient cost reimbursement level (e.g., AWP – 10%) and the dispensing fee (e.g., $4.76 in Nevada in 2004) that determines the net reimbursement to a retail pharmacy for dispensing a Medicaid

prescription. *See* AstraZeneca 56.1 Stmt. ¶ 28. Further, it is undisputed that Nevada pharmacies are not fully compensated for their dispensing costs by the dispensing fee paid by the State's Medicaid program and, as a result, would lose money on every Medicaid-covered drug they dispensed if they were forced to rely solely on the dispensing fee to cover their costs. *See* Joint Mem. at 21, n. 15. Taking the inadequate dispensing fee into account, the Nevada Medicaid program *knowingly* sets reimbursement rates for drug ingredient costs at levels that provide a profit margin to these pharmacies. *See id*.; Joint 56.1 Stmt. ¶ 84-85, 88. In other words, the Nevada Medicaid program knowingly cross-subsidizes the underpayment of dispensing fees through its ingredient cost reimbursement rates. Such a system has persisted even after the State filed its complaint in this action.

Mr. Winterton analyzed the Medicaid reimbursements paid by the State for AstraZeneca's top five drugs in 2004 to determine—given the underpayment of dispensing fees—whether Nevada pharmacies were in fact making large profits on dispensing AstraZeneca's Medicaid-covered drugs. In stark contrast to the State's unsupported allegations, Mr. Winterton finds that Nevada pharmacies were in fact incurring a small to substantial *loss* in dispensing these AstraZeneca drugs. *See* AstraZeneca 56.1 Stmt. ¶¶ 10, 13, 14. For example, Mr. Winterton determines that, in 2004, Nevada pharmacies incurred a net average loss of roughly 3 percent in dispensing AstraZeneca's top five drugs under the State's Medicaid program—when the underpayment of dispensing fees is taken into account. *Id.* ¶ 13. Further, in Dr. Hartman's "but for" world, which requires that actual acquisition costs for drugs equal the State's estimated acquisition costs ("EACs"), Nevada pharmacies would have realized a net loss of approximately 4 percent in dispensing AstraZeneca drugs *Id.* ¶ 22.

Clearly, Nevada pharmacies were not realizing windfall profits in dispensing AstraZeneca drugs to Medicaid beneficiaries. Taking into account the legal requirements of the equal access provision, Nevada's Medicaid program had little—if any—room to lower its ingredient cost reimbursement rates and still keep a sufficient number of pharmacies servicing its Medicaid beneficiaries . Thus, because the State could not have realistically lowered its reimbursement rates for AstraZeneca's Medicaid-covered products—without Nevada pharmacies suffering additional losses each time they dispensed such a product—there was no ascertainable loss suffered by the State as a result of AstraZeneca's alleged misconduct.

C. AstraZeneca Should be Granted Summary Judgment on the State's "Best Price" Claims Related to Zoladex

The State's "Best Price" allegations concerning Zoladex refer to a criminal investigation that allegedly "revealed that AstraZeneca knowingly misreported and underpaid Medicaid rebates for Zoladex by failing to include in its reported Best Price off invoice price concessions provided in various forms including, but not limited to, cash discounts in the form of grants, services, free goods contingent on a purchase requirement, volume discounts and rebates." Am. Compl. ¶ 399.

There are no facts or evidence in the record whatsoever to support Plaintiff's bald allegations. Indeed, the State fails to allege how or why the "Best Price" rebates paid to it by AstraZeneca were adversely affected by AstraZeneca's alleged misconduct. Nevada's complete failure of proof warrants summary judgment for AstraZeneca on the State's "Best Price" claims relating to Zoladex. *See Celotex*, 477 U.S. at 323 (holding that a complete failure of proof concerning an essential element of the non-moving party's case necessarily renders all other facts immaterial).

Moreover, the AstraZeneca guilty plea referred to by the State in its Amended Complaint, Am. Compl. ¶¶ 399-400, does not support the State's "Best Price" claims. The guilty plea pertains only to violations of the Prescription Drug Marketing Act ("PDMA"), which prohibits the sale, purchase, or trade of drug samples. *See* 21 U.S.C. § 353(c)(1). AstraZeneca's plea to a violation of the PDMA in no way satisfies the State's burden to present evidence sufficient to support its allegations that AstraZeneca's rebates to the State were too small during any period, much less the entire ten-plus year period at issue in this case.

CONCLUSION

For the foregoing reasons, as well as those set forth in Defendants' Joint Memorandum, AstraZeneca is entitled to summary judgment on all of the State of Nevada's claims.

February 8, 2007

Dated: Boston, Massachusetts
February 8, 2007

Respectfully Submitted,

By: /s/ Katherine B. Schmeckpeper

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CERTIFICATE OF SERVICE

I hereby certify that on February 8, 2007, I caused a true and correct copy of the foregoing, Declaration of James J. Duffy in Support of the Individual Memorandum of Law in Further Support of AstraZeneca Pharmaceuticals LP's Motion for Summary Judgment, to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 in MDL No. 1456.

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